

DRUG FOR VETERINARY USE

5464. Bacitracin ointment (veterinary). (F.D.C. No. 40873. S. No. 78-016 M.)

QUANTITY: 3,216 boxes, each containing 1 syringe, at Lincoln, Nebr.

SHIPPED: 8-16-57, from Inglewood, Calif., by Delta Laboratories.

LABEL IN PART: "Mitox Active Ingredients Per Syringe Bacitracin 3200 Units * * * Veterinarians only * * * Control No. 2175 Expiration Date: Feb. '59."

RESULTS OF INVESTIGATION: Examination showed that the article contained substantially less bacitracin than the label declared.

LIBELED: 10-25-57, Dist. Nebr.

CHARGE: 501(c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess, namely, 3,200 units per syringe; and 502(a)—the label statement "Per Syringe Bacitracin 3200 Units" was false and misleading; and 502(1)—the article contained bacitracin, and it was not from a batch with respect to which a certificate or release had been issued.

DISPOSITION: 12-5-57. Default—destruction.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS*

5465. Penicillin. (F.D.C. No. 40934. S. Nos. 76-701/2 M.)

QUANTITY: 47 10-cc. vials and 97 10-cc. vials at Millbury, Mass.

SHIPPED: 3-25-57 and 4-2-57, from Baltimore, Md.

LABEL IN PART: (47-vial lot) "10 cc Crystalline Procaine Penicillin G in Aqueous Suspension 300,000 units per cc"; (97-vial lot) "1,000,000 Units Potassium Penicillin Crystalline 'G'."

RESULTS OF INVESTIGATION: The article was in the possession of a dealer in veterinary supplies, and its labeling did not bear adequate directions for use in the treatment of animals.

LIBELED: 11-4-57, Dist. Mass.

CHARGE: 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use; and 503(b)(4)—the article was not intended for use by man, and its label bore the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 12-16-57 and 12-24-57. Default—destruction.

5466. X 100 Cosmetic Solution. (F.D.C. No. 40623. S. No. 41-877 M.)

QUANTITY: 2 1-gal.-size btls., each containing $\frac{2}{3}$ of a gal.; 21 btls., each containing 1 oz.; and 10 btls., each containing $\frac{1}{2}$ oz., at Buffalo, N.Y.

SHIPPED: 5-15-57, from Detroit, Mich., by R. Tacon.

LABEL IN PART: (1-gal. btls.) "X 100 Cosmetic Solution Contains 10,000 I.U. Δ 1, 3, 5, Estratriene a 3,17 Diol per oz. For External Use Only Distributed by R. Tacon Detroit Mich."

RESULTS OF INVESTIGATION: The article in the 1-oz. and $\frac{1}{2}$ -oz. btls. was re-packed by the dealer from the 1-gal. btls. described above. The article was employed by the dealer as a hair and scalp treatment, consisting of the application of $\frac{1}{2}$ -fluid oz. to the hair and scalp as a single "treatment."

*See also Nos. 5461, 5463.

Analysis showed that the article consisted of isopropyl alcohol, containing 1.5 mg. of estradiol and 1.8 mg. of alpha-estradiol per fluid ounce.

LIBELED: 8-30-57, W. Dist. N.Y.

CHARGE: 502(e) (2)—when shipped and while held for sale, the label of the article failed to bear the common or usual name of each active ingredient and the proportion of isopropyl alcohol contained in the article; 502(f) (1)—the labeling of the article failed to bear adequate directions for use, and it did not comply with any of the exempting regulations; and 503(b) (4)—the article was a drug subject to 503(b) (1), and its labeling failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 10-1-57. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

5467. Nutrilite food supplement. (F.D.C. No. 40605. S. No. 30-785 M.)

INFORMATION FILED: 1-6-58, S. Dist. Ohio, against P. E. Lockwood and Harley A. Dudgeon, Kings Creek, Ohio.

ALLEGED VIOLATION: In the course of a sales talk given at Kings Creek, Ohio, on 7-10-57, the defendants made oral representations to the persons present, holding the article out as a treatment for ulcers, rheumatoid arthritis, strokes, high blood pressure, varicose veins, migraine headaches, asthmatic conditions, prostate trouble, eye trouble, and calming the nerves.

LABEL IN PART: (Pkg.) "Nutrilite Junior Food Supplement This package contains multiple vitamin capsules and mineral tablets for use as a dietary food supplement to fortify, or supplement, the diet."

CHARGE: 502(f) (1)—the label of the article failed to bear adequate directions for use in the treatment of the diseases, symptoms, and conditions for which it was intended, namely, the diseases, symptoms, and conditions set forth above.

PLEA: Guilty.

DISPOSITION: 1-27-58. Each defendant fined \$250.

5468. Oil of wintergreen and aspirin tablets. (F.D.C. No. 40950. S. Nos. 48-754/5 M.)

QUANTITY: 1 55-gal.-size drum containing 4 gals., and 125 doz. 1-oz. btls., 97 doz. 2-oz. btls., 33 doz. 4-oz. btls., and 5 1-gal. jugs of *oil of wintergreen*, and 152 cases, each containing 6 doz. 100-tablet btls., of *aspirin*, at Chicago, Ill., in possession of Dr. Sachs Laboratories.

SHIPPED: Between 7-6-57 and 10-31-57, from Lyndhurst and Newark, N.J., and Norwich, N.Y.

LABEL IN PART: (Btl.) "Oil of Wintergreen (Methyl Salicylate) U.S.P. Synthetic" and "Health-A-Teria Aspirin 5 Grains Each Acetylsalicylic Acid U.S.P. * * * Packed for Health-A-Teria, Inc., Chicago, Illinois."

RESULTS OF INVESTIGATION: The *oil of wintergreen* and the *aspirin tablets* in the above-mentioned btls. were repacked by the consignee from bulk stock shipped as described above.

LIBELED: 11-12-57, N. Dist. Ill.; amended 11-21-57.

*See also Nos. 5462, 5463, 5465, 5466.